

REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

By the foregoing amendments claims 1, 2, 4-8, 10-15 and 17-36 are cancelled and claims 37-98 are added, whereby claims 37-98 will be pending, with claims 37 and 69 being independent claims.

Support for the new claims can be found throughout the present specification and in particular, the original claims and pages 3, 9-11, 15, 16, 18, 19 and 24 of the specification.

Applicants emphasize that the cancellation of claims 1, 2, 4-8, 10-15 and 17-36 is without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute the cancelled claims in one or more continuation and/or divisional applications.

Summary of Office Action

Claims 1, 4, 5, 7, 8, 10-15, 17, 18, 20-30 and 33-36 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lucast et al. U.S. Patent No. 6,479,073 (hereafter "LUCAST I") in view of Merkle et al., U.S. Patent No. 5,527,536 (hereafter "MERKLE") and Lucast et al., U.S. Patent No. 5,407,717 (hereafter "LUCAST II"), and further in view of Koketsu et al., U.S. Patent No. 5,547,223 (hereafter "KOKETSU").

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Claim 2 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LUCAST I in view of MERKLE and further in view of Wildeman et al., U.S. Patent No. 3,967,472 (hereafter "WILDEMAN").

Claim 6 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LUCAST I in view of MERKLE, LUCAST II, and KOKETSU, and further in view of Bodenschatz et al., U.S. Patent No. 6,074,965 (hereafter "BODENSCHATZ").

Claim 19 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LUCAST I in view of MERKLE, LUCAST II, and KOKETSU, and further in view of Seabold et al., U.S. Patent No. 4,315,047 (hereafter "SEABOLD").

Claims 31 and 32 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LUCAST I in view of MERKLE, LUCAST II, and KOKETSU, and further in view of Kantner et al., U.S. Patent No. 5,489,624 (hereafter "KANTNER").

Claims 1, 2, 4-8, 10-15 and 17-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,555,730 to Albrod et al. (hereafter "ALBROD") in view of MERKLE.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested in view of the foregoing amendments and the following remarks.

Response to Rejection of Claims 1, 4, 5, 7, 8, 10-15, 17, 18, 20-30 and 33-36 under 35 U.S.C. § 103(a)

Claims 1, 4, 5, 7, 8, 10-15, 17, 18, 20-30 and 33-36 are rejected under 35 U.S.C. §

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103(a) as allegedly being unpatentable over LUCAST I in view of MERKLE and LUCAST II, and further in view of KOKETSU. The rejection alleges that LUCAST I discloses a medical tape for use on human skin and that this document teaches that the substrate layer may be a nonwoven fabric including stitch-bonded fabrics. The rejection further asserts that the adhesive composition of LUCAST I may comprise a styrene block copolymer.

The rejection concedes that LUCAST I does not teach a pharmacologically active agent to be present in the adhesive composition. In this regard, the rejection points to MERKLE which is alleged to disclose a medical patch for controlled release of pharmacologically active agents. According to the rejection, the adhesive of MERKLE comprises a block copolymer that comprises polystyrene for one block and a mixture of ethylene and butylenes for another block. Based on the foregoing assertions, the rejection alleges that it would have been obvious to a person having ordinary skill in the art to incorporate a pharmacologically active agent into the tape of LUCAST I in order to provide the tape with an enhanced medical function, as allegedly taught by MERKLE.

Further, the Examiner takes the position that the remaining features recited in the rejected claims are allegedly disclosed in LUCAST II or KOKETSU or are allegedly inherent in the teachings of the cited documents.

Applicants respectfully traverse this rejection. In particular, Applicants are unable to verify the Examiner's contention that the adhesive composition of LUCAST I may comprise a styrene block copolymer. The passage of LUCAST I relied on in the present Office Action in this regard, i.e., col. 4, lines 17-21 (see top of page 4 of the Office Action) does not support this contention. In particular, col. 4, lines 17-26 of LUCAST I states:

The alkyl acrylate monomers can be used to form homopolymers, or they can be copolymerized with polar copolymerizable monomers or higher T_g monomers (higher than the alkyl acrylate) such as some vinyl esters, and C₁ to C₄ alkyl esters of (meth)acrylic acid and/or styrene. When copolymerized with polar monomers, the alkyl acrylate monomer generally comprises at least about 70% of the polymerizable monomer composition. A portion of high T_g monomers can be used as long as the T_g of the resulting copolymer is less than about 10° C.

The above passage does not mention block copolymers, let alone styrene block copolymers. While styrene is mentioned as one of several possible comonomers for producing alkyl acrylate copolymers, it would appear that the corresponding copolymers are intended to be (conventional) random copolymers rather than block copolymers.

The above passage is preceded by a general discussion of the matrix polymer of the adhesive of LUCAST I which states that among the suitable materials for the matrix the acrylic adhesives are less prone to discoloration and are amenable to a precise control during preparation (col. 3, line 66 to col. 4, line 6). In line therewith, the matrix polymers employed in the numerous Examples of LUCAST I are alkyl acrylate copolymers, i.e., a copolymer of iso-octyl acrylate, acrylic acid and polyethylene oxide acrylate (70/15/15), a copolymer of iso-octyl acrylate and acrylamide (97/3), a copolymer of iso-octyl acrylate, acrylic acid and 2-polystyrylethyl methacrylate macromonomer (96/2/2), and a copolymer of iso-octyl acrylate, vinyl acetate, acrylic acid and 1,6-hexanediol diacrylate (89/6/6/2). See col. 16, lines 10-46 of LUCAST I.

MERKLE, on the other hand, calls for an adhesive which must not only contain a styrene block copolymer, but a very specific styrene block copolymer, i.e., a triple-block copolymer of polystyrene block copoly(ethylene/butylene) block polystyrene (SEBS). See, e.g., abstract of MERKLE.

Since LUCAST I does not appear to mention styrene block copolymers as part of the

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adhesive thereof, let alone as essential part, but rather recommends acrylic homo- and copolymers, whereas MERKLE calls for a specific styrene block copolymer, i.e, a polystyrene block copoly(ethylene/butylene) block polystyrene (SEBS), there is no motivation for one of ordinary skill in the art to employ the styrene block copolymer of MERKLE as matrix for the adhesive of LUCAST I, let alone to replace the adhesive of LUCAST I which comprises a blend of discrete, crosslinked polymer microspheres and a polymer matrix by the apparently homogeneous, pharmacologically active agent containing hot-melt adhesive of MERKLE. For this reason alone, LUCAST I and MERKLE fail to render obvious the subject matter of any of the claims submitted herewith. There are, however, further reasons as well.

In particular, even if one were to assume, *arguendo*, that col. 4, lines 17-26 of LUCAST I discloses styrene block copolymers (which it clearly does not), these block copolymers would be styrene-alkyl acrylate block copolymers (Applicants are not aware of the existence of such block copolymers) which would still be significantly different from the polystyrene block copoly(ethylene/butylene) block polystyrene (SEBS) copolymers of MERKLE. Specifically, due to the presence of polar alkyl acrylate blocks, one of ordinary skill in the art would assume that the block copolymers of LUCAST I have properties which are significantly different from those of the block copolymers of MERKLE which consist of exclusively non-polar components.

Further, MERKLE does not mention nonwovens, let alone stitch-bonded nonwovens, as a possible substrate for the active substance containing adhesive described therein at all. In fact, possible substrates (backing layers) are not specifically addressed in MERKLE at all. Applicants note that, in all of the Examples of MERKLE a

polyester film is used as backing layer.

LUCAST I states the following with respect to suitable medical substrate materials for the adhesive compositions disclosed therein (col. 3, lines 19-37):

The adhesive compositions of the present invention are particularly suitable for the production of medical articles intended for adhesion to skin. Examples include tapes, skin patches, strips, wound dressings, monitoring or neuro-stimulating electrodes, transparent adhesive dressings, island dressings (with absorbent polymeric or fabric islands), consumer first aid dressings, drapes, and the like. Suitable substrates for these applications include conformable backing materials that are known in the medical or surgical fields. Useful substrates include nonwoven fabrics, woven fabrics, knit fabrics, and low to medium tensile modulus synthetic films such as polypropylene, polyethylene, polyvinyl chloride, polyurethane, low modulus polyester and ethyl cellulose. Fabrics can be made from materials such as cotton, nylon, rayon or other natural or synthetic fibers or blends. The films preferably have a tensile modulus less than about 400,000 psi as measured in accordance with ASTM D-638 and D-882 procedures, preferably less than about 300,000 psi.

Accordingly, LUCAST I mentions nonwoven fabrics only as one example of a number of possible substrate materials. Even if one were to assume that the statement in the paragraph bridging columns 2 and 3 of LUCAST I that "suitable non-woven fabrics include carded, spun-bonded, spun-laced, air-laid, blown microfibrous constructions, and stitch-bonded fabrics" applies to the nonwoven fabrics which are useful substrates for medical articles (i.e., not only to nonwoven materials for flexible substrates in general), LUCAST clearly does not provide any particular motivation to use nonwoven fabrics as substrate materials, let alone stitch-bonded nonwoven fabrics.

In this regard, Applicants also note that the only substrate materials used in the numerous Examples of LUCAST are a polyurethane blown microfiber backing, a polyester (film?) backing, and a polyurethane film (MorthaneTM PE-44-203) backing, i.e., substrates which do not bear any resemblance to a nonwoven fabric, let alone a stitch-bonded

nonwoven fabric. This is in line with the teaching in col. 3, lines 52-61 of LUCAST I:

Preferred substrates have a high rate of moisture vapor transmission. For example, a continuous film substrate of 25 μm thickness prepared from a polyurethane sold under the tradename Estane 58309, available from B. F. Goodrich, and a continuous film substrate prepared from a polyester sold under the tradename Hytrel 4053, available from DuPont, each have moisture vapor transmission values of about 1000 to about 1500 $\text{g/m}^2/24$ hours. Woven substrates such as those used for DURAPORETM tape, available from 3M, have even higher values.

Emphases added. Accordingly, even if one were to combine the teachings of LUCAST I and MERKLE, there would be no motivation to use a nonwoven fabric as substrate material, let alone a stitch-bonded nonwoven fabric. On the contrary, since MERKLE does not mention nonwoven fabrics at all and LUCAST I mentions them only among a large number of possible substrate materials and expressly recommends substrate materials which are significantly different from (stitch-bonded) nonwoven fabrics, Applicants submit that one of ordinary skill in the art would not seriously contemplate using a stitch-bonded nonwoven fabric in combination with the adhesive composition of LUCAST I, let alone with the adhesive composition of MERKLE.

Even further, it also is to be taken into account that the adhesive of LUCAST I comprises not only a matrix, but also discrete crosslinked polymer microspheres incorporated into said matrix (see, e.g., abstract of LUCAST I). This constitutes an additional disincentive to employ the adhesive composition of MERKLE instead of the matrix polymer of LUCAST I.

For at least all of the foregoing reasons, LUCAST I in view of MERKLE does not render it obvious to provide an adhesive composition of the type recited in present independent claims 37 and 69 on a stitch-bonded nonwoven as recited in independent

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claims 37 and 69.

In view of the circumstances set forth above it does not appear necessary to discuss whether any of the remaining elements recited in the present independent claims and in the dependent claims submitted herewith are rendered obvious by any of LUCAST I in view of MERKLE, LUCAST II and KOKETSU. Applicants' silence in this regard is not to be construed, however as an admission that any of the allegations set forth in the present Office Action are of merit. By way of example, Applicants respectfully submit that the statement at the bottom of page 5 of the present Office Action according to which LUCAST I discloses using polyisoprene as a possible block polymer with polystyrene is (also) clearly incorrect. The passage of LUCAST I relied on in this regard, i.e., col. 4, lines 35-43 reads:

Optionally, a low molecular weight hydrophobic polymer can be added to the adhesive matrix monomers to improve emulsion stability. These polymers preferably have an average molecular weight from 400 to 50,000 and include polystyrene resins, poly(methylmethacrylate) resin, polybutadiene, polyisoprene, poly(alphamethylstyrene), polydiene-polyaromatic arene copolymers, rosin esters and mixtures thereof. These may be added in amounts up to 20% of the monomer mixture, preferably up to 10%.

Emphases added. The above statement obviously has nothing at all to do with the preparation and/or use of a polystyrene-polyisoprene block copolymer.

Applicants also would like to point out that it is not understood why a material that is used as a medical tape is (necessarily) tearable, as is alleged in the present Office Action at page 5, beginning of second paragraph. The reasoning underlying the rejections of claims 4, 10, 25 and 26 is also completely unclear to Applicants.

To sum up, in view of the foregoing the claim rejection under 35 U.S.C. § 103(a) over LUCAST I in view of MERKLE and LUCAST II, and further in view of KOKETSU is clearly without merit and should be withdrawn, which action is respectfully requested.

Response to Rejection of Claims 2, 6, 19, 31 and 32 under 35 U.S.C. § 103(a)

Claims 2, 6, 19, 31 and 32 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LUCAST I in view of MERKLE and various other documents. As set forth in detail above, the rejections based on LUCAST I in view of MERKLE are unfounded. Accordingly, the rejection of claims 2, 6, 19, 31 and 32 over these documents is necessarily unfounded as well and should be withdrawn. In view thereof, Applicants refrain from commenting on the corresponding allegations set forth in the present Office Action. However, Applicants' silence in this regard is not to be construed as an admission that any of these allegations are meritorious.

Response to Obviousness-Type Double Patenting Rejection

Claims 1, 2, 4-8, 10-15 and 17-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of ALBROD in view of MERKLE.

Applicants respectfully request that this rejection be held in abeyance until an agreement on the wording of allowable claims has been reached. Thereafter, Applicants will decide whether the filing of a Terminal Disclaimer is appropriate.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

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